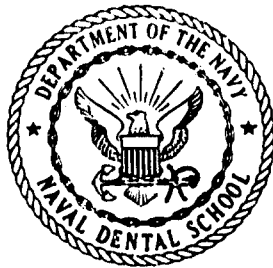


AD713118

NDS-TR-017
1 September 1970



IMPRESSION MATERIAL STERILIZATION WITH
GASEOUS ETHYLENE OXIDE

by

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ABSTRACT

The increase in surgical treatment of oral, facial, and cranial defects has prompted a concomitant increase in requests for impressions to be made in the surgical theater. To avoid violation of the sterile chain, impression materials and equipment should be sterile. Irreversible hydrocolloid and plaster materials are practical for use in the operating room but cannot be sterilized by autoclaving and other high temperature methods; and whether they are sterile as received from the manufacturer is questionable. The purpose of this study was to determine the effectiveness of gaseous ethylene oxide treatment in sterilizing hydrocolloid powder and fast-setting plaster; and to determine the effect of the procedure on the physical properties of the hydrocolloid. Spores of Bacillus subtilis var. globigii were mixed with the respective materials to yield a spore concentration of about 1.0×10^8 colony-forming units per gram of powder. Samples of 20 to 40 grams of powder in envelopes were subjected for 48 minutes to ethylene oxide gas in a 1-cubic-foot capacity Steri-Vac unit. After 48 hours of airing, the samples were assayed for microorganisms, and setting time and duplicating properties of the material were tested. No bacteria were recovered from the 30 samples of each type of material exposed to ethylene oxide gas, but they were recovered from control samples not exposed to the gas. Both materials were found to be contaminated with gram-positive bacilli and cocci as received from the manufacturer. There was no significant difference between setting times and linear measurements of sterilized and nonsterilized samples.

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INTRODUCTION

The increase in surgical treatment of oral, facial, and cranial defects has prompted a concomitant increase in requests for impressions to be made in the surgical theater. To avoid violation of the sterile chain, sterile impression materials and equipment should be used.

Irreversible hydrocolloid is one of the most practical impression materials for use in the operating room. The equipment (mixing bowl, spatula, and measuring devices) is simple and easily sterilized, and no electricity or open flame is required. Trays to contain the material can be constructed in any size or shape with acrylic resin; or the hydrocolloid can be backed and supported with fast-setting plaster. Although some decrease in dimensional accuracy may result, alginate's flow properties and setting time can be conveniently altered by changing the water-powder ratio and the water temperature. Mazaheri and Sahni¹ have described manipulation of the material in fabrication of serial diagnostic casts and moulages for cleft palate patients. Both irreversible hydrocolloid² and plaster deteriorate rapidly at elevated temperatures and in the presence of moisture, so they cannot be sterilized by autoclaving and other high temperature methods. A practical means of sterilizing these materials is needed since it is questionable whether they are sterile as received from the manufacturer.

Gaseous ethylene oxide is an effective sterilizing agent at temperatures considerably lower than those attained in an autoclave or in a dry-heat sterilizer. For this reason, it is used to sterilize materials easily destroyed by high temperatures.³ The purpose of this study was to determine the effectiveness of gaseous ethylene oxide treatment in sterilizing hydrocolloid powder and fast-setting plaster and to determine the effect of the procedure on the physical properties of the hydrocolloid material.

MATERIALS AND METHODS

Tests for the effectiveness of sterilization procedures were made using the resistant spores of Bacillus subtilis var. globigii. The spores were mixed with type II normal-setting irreversible hydrocolloid powder* and a fast-setting plaster material† to yield a concentration of about 1.0×10^8 colony-forming units per gram of powder. Artificially contaminated aliquots of 10 to 30 grams (three units with the manufacturer's measure) of hydrocolloid powder and 30 to 40 grams (two units with the manufacturer's measure) of plaster material were transferred to paper sterilizing envelopes.* A total of 30 envelopes for each type of material

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*Caulk, Jeltrate, Alginate Impression Material, L. D. Caulk Co., Milford, Del.

†Kerr Manufacturing Co., Detroit, Mich.

‡American Hospital Supply Corp., Cat. No. 6530-754-0421 Edison, N. J.

were exposed, in six separate trials, to gaseous ethylene oxide* for 48 minutes in a sterilizing unit† with a capacity of 1 cubic foot. The envelopes were then aired in an open area for 48 hours at room temperature for removal of residual ethylene oxide material.

The samples of hydrocolloid and plaster powders that had been exposed to ethylene oxide gas were then assayed for microbial contamination. About 1 gram of powder from each envelope was aseptically transferred to a separate tube of trypticase soy broth.‡ Turbidity could not be used as a criterion of bacterial growth because the broth-powder mixture was already turbid before incubation. Therefore, 0.1 ml amounts of the mixture were plated with trypticase soy agar§ pours (1) immediately, and (2) after incubation of the original mixture for 24 hours at 37° C. Contamination or noncontamination of the materials was determined by the presence or absence of colonies in the agar medium and by microscopic examination for organisms using Gram staining procedures. Thirty control samples of the artificially contaminated materials were simultaneously subjected to the same assay procedure but without previous exposure to ethylene oxide. To determine whether the hydrocolloid powder and the plaster were contaminated as received from the manufacturer, samples were removed aseptically from three freshly opened packages of each type of material and assayed in the same manner.

The effect of the sterilizing procedure on the physical properties of the irreversible hydrocolloid material was evaluated by testing for setting time and accuracy of duplication. A total of 30 samples were subjected to a test for setting time as set forth in American Dental Association Specification No. 18.¶ A total of 10 nonsterilized control samples were subjected to the same test for comparison. Accuracy of duplication was tested on samples from 18 envelopes filled with irreversible hydrocolloid powder previously exposed to gaseous ethylene oxide. The test consisted of using the material mixed from the powder in each envelope to make an impression of an acrylic resin rectangular form utilizing a specially adapted perforated metal tray. The impressions were poured with a standard mix of dental stone. Five additional impressions of the rectangle were made from nonsterilized alginate and poured in the same manner. The casts were then measured lineally with a micro-measuring device.®

RESULTS

Bacterial growth was not observed in any of the artificially contaminated hydrocolloid or plaster samples exposed to gaseous ethylene oxide, but the unexposed samples were all contaminated with the test

*Steri-Gas Cartridge (one cartridge per run contained 30 grams of 100% ethylene oxide material)

†Steri-Vac Sterilizer Model H100 3M Co., St. Paul, Minn.

‡Baltimore Biological Laboratories, Baltimore, Md.

§Central Scientific Co., Newark, N.J.

bacterium. The samples of hydrocolloid and plaster as received from the manufacturer were all found to be contaminated with gram-positive bacilli and cocci.

The effect of gaseous ethylene oxide sterilizing procedures on the physical properties of hydrocolloid material is shown in table 1. There was no significant difference in setting time and linear measurement between the materials mixed from the sterilized and nonsterilized powder samples.

Table 1.--Effect of gaseous ethylene oxide sterilizing procedures on physical properties of irreversible hydrocolloid

	Setting time (min)	Linear measurement of casts (mm)
Control (nonsterilized)	3.5 ± 0.1 (10)*	54.92 ± 0.03 (5)*
Experimental (sterilized)	3.5 ± 0.1 (30)*	54.93 ± 0.04 (18)*

*No. of powder samples

DISCUSSION

It is not known whether the contamination present in the hydrocolloid and plaster powder as they are received from the manufacturer represents a potential health hazard in routine clinical use. Procedures involving surgery, however, demand the use of sterile impression materials. In this respect, ethylene oxide was shown to be very effective. Although gaseous ethylene oxide is widely used to sterilize many materials, its use for sterilizing hydrocolloid powder has not previously been reported. Gaseous ethylene oxide as a sterilizing agent is known to have excellent penetrating properties, and it leaves no residual chemical when materials are aired for adequate periods.³ The packaging of powder in small amounts, e.g., three measures, provides convenient quantities for practical use and at the same time provides a small bulk for maximum penetration of the gaseous agent. The foregoing results indicate that the ethylene oxide procedure is effective in sterilizing hydrocolloid and plaster materials even when they contain resistant spores. Furthermore the sterilization procedure does not adversely affect the setting time and linear dimensions of the hydrocolloid material.

The sterilization method used in this study showed itself to be effective and practical. The making of impressions of surgical defects under sterile conditions--for procedures such as cranioplasty.

tympanoplasty, and oculooplasty--now seems feasible. The fabrication of therapeutic contact lenses, skin graft splints, and neonatal cleft palate prostheses are other procedures that warrant the use of sterile impression materials.

SUMMARY

In this study, 30 samples of one type of irreversible hydrocolloid powder and 30 samples of one type of plaster material were sterilized using gaseous ethylene oxide. The procedure did not adversely affect the setting time or the dimensional accuracy of the hydrocolloid material.

ACKNOWLEDGMENTS

The authors acknowledge with thanks the technical assistance of Dental Technician Second Class R. P. Poe, USN, and Dental Technician Third Class R. E. Hess, USN.

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Security Classification

DOCUMENT CONTROL DATA - R&D		
(Security classification of title, body of abstract and indexing annotation must be entered when the overall report is classified)		
1. ORIGINATING ACTIVITY (Corporate author) Naval Dental School National Naval Medical Center Bethesda, Maryland 20014		2a. REPORT SECURITY CLASSIFICATION UNCLASSIFIED
		2b. GROUP
3. REPORT TITLE IMPRESSION MATERIAL STERILIZATION WITH GASEOUS ETHYLENE OXIDE		
4. DESCRIPTIVE NOTES (Type of report and inclusive dates)		
5. AUTHOR(S) (Last name, first name, initial) D. N. Firtell, Commander, DC, USN, D. J. Moore, Commander, DC, USN, G. B. Pelleu, Jr., Ph.D.		
6. REPORT DATE 1 September 1970	7a. TOTAL NO. OF PAGES 4	7b. NO. OF REFS 4
8a. CONTRACT OR GRANT NO.	9a. ORIGINATOR'S REPORT NUMBER(S) NDS-TR-017	
a. PROJECT NO.		
c.	9b. OTHER REPORT NO(S) (Any other numbers that may be assigned this report)	
d. WORK UNIT NO. MR005.20-6053		
10. NO RELEASE TO THE PUBLIC DISTRIBUTION STATEMENT This document has been approved for public release and sale; its distribution is unlimited.		
11. SUPPLEMENTARY NOTES	12. SPONSORING MILITARY ACTIVITY BUREAU OF MEDICINE AND SURGERY Navy Department Washington, D.C. 20390	
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14	KEY WORDS	LINK A		LINK B		LINK C	
		ROLE	WT	ROLE	WT	ROLE	WT
	Contamination Ethylene oxide gas Impression materials Sterilization						

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Security Classification